

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS
et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendant.

Civil Action No. 16-cv-11985-IT

JOINT REPORT ON ENTRY OF FINAL JUDGMENT

On January 23, 2020, this Court ordered counsel to submit a joint report setting forth any remaining issues that need to be addressed before a final judgment is entered in this action [#66]. Counsel for the plaintiffs and for the defendant United States Food and Drug Administration (“FDA”) have conferred, but they were unable to agree upon the answer to the Court’s question. Accordingly, after setting forth an agreed-upon statement of the procedural context, each side offers a separate response to the Court’s inquiry.

Procedural Context. The Court’s March 5, 2019 Order [#56] recited the Court’s earlier determination that FDA had “unlawfully withheld” and “unreasonably delayed” agency action, and that pursuant to the Administrative Procedure Act, 5 U.S.C. § 706(1), the Court was obliged to compel agency action [#56 at 2, citing Mem. & Order [#50] at 2, 15]. As subsequently amended on March 21, 2019 [#59], the Court’s March 5, 2019 Order [#56] enjoined FDA to complete a pending study by May 16, 2019, to submit a notice of proposed rulemaking for publication in the Federal Register by August 15, 2019, and to submit a final rule for publication in the Federal Register by March 15, 2020. FDA met the first two deadlines, *see Tobacco*

Products; Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg. 42754-01 (Aug. 16, 2019), and FDA has likewise advised the plaintiffs that it expects to meet the remaining deadline of March 15, 2020.

Plaintiffs' Position. It is the plaintiffs' position that there are no remaining issues that need to be addressed before a final judgment is entered in this action. If FDA submits its final rule for publication by March 15, 2020 as previously ordered by the Court, the only remaining matter that may come before this Court is a post-judgment motion for attorneys' fees by the plaintiffs under the Equal Access to Justice Act ("EAJA"), 28 U.S.C. § 2412(b). If FDA fails to meet the March 15, 2020 deadline for submission of its final rule for publication in the Federal Register, the plaintiffs can be expected to move for an enforcement order by this Court. Neither of these potential future issues needs to be addressed before final judgment is entered. The EAJA, in fact, contemplates that motions for fees will be submitted *after* entry of judgment. *See* 28 U.S.C. § 2412(d)(1)(B). If the Court determines that final judgment should be entered at this juncture, the plaintiffs stand ready to submit a proposed form of final judgment for the Court's consideration.

FDA's Position. FDA respectfully suggests that the Court maintain the status quo for the several weeks that remain under the order of injunction, to allow for the possibility that something unexpected might arise and a party might need to address the Court. (As stated above, FDA continues to anticipate meeting the March 15, 2020, deadline.) FDA does not oppose administrative closure of this case should the Court decide to do so in the interim.

January 30, 2020

Respectfully submitted,

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Certificate of Service

I hereby certify that this document filed through the ECF system was sent electronically to all counsel of record on January 30, 2020.

/s/ Jessica A. Wall